UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,979	03/24/2004	Assaf Govari	BIO-5044	4469

27777 7590 02/27/2006

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,979	GOVARI, ASSAF	
	Examiner	Art Unit	
	Peter J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-2-5;3-24-4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The application is published application number: 2005/0215 990. The publication is classified in US 606/27.

The Applicant is requested to provide (or check for accuracy) at the beginning of the Specification updated status information (serial numbers and patent numbers) of all related applications. The effective filing date of this application is 3-24-04.

Pending claims as of 3-24-04 are 1-22.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3-24-04 (9-2-05) is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3, 4, 5, 6, 7, 8, 9, 12, 16, 18 and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Sliwa, Jr. et al. (6,971,394).

Sliwa discloses:

1. Apparatus (see figure 64, *inter alia*) for use with a subject, comprising: a catheter (see figure 8, *inter alia*) having a longitudinal axis and having a distal portion; and an ultrasound array (406) fixed to the distal portion, adapted to operate in a phased array mode (col. 29:26-30) to apply ablating energy to tissue of the subject located in a range of azimuths (note transducer/tissue angle flexibility depicted in figure 67 and disclosed in col. 30:55-65), with respect to the longitudinal axis, that is less than 360 degrees (this a near complete range of motion – barely limiting).

3. The apparatus according to claim 1, wherein the ultrasound array is adapted to apply the ablating energy to tissue in a range of azimuths between about 180 and 359 degrees (note transducer/tissue angle flexibility depicted in figure 67 and disclosed in col. 30:55-65).

4. The apparatus according to claim 1, wherein when the catheter is disposed in a vicinity of an ostium of a pulmonary vein (col. 2:57-60, *inter alia*) of the subject, the range of azimuths is sufficiently smaller than 360 degrees to avoid inducing a deficit in a phrenic nerve (col. 17:25-30; col. 2:22) of the subject.

5. The apparatus according to claim 1, comprising detection functionality (imaging disclosed in col. 3:53-57, col. 16:30-33, col. 16:53-56, and col. 34:51), adapted to determine tissue of the subject that is not to be targeted by the ablating energy (visualization / imaging certainly does this), wherein the ultrasound array is adapted to (control system 334; col. 34:45-57) configure the ablating energy responsive to the determination of the tissue that is not to be targeted.

6. The apparatus according to claim 5, wherein the ultrasound array is adapted to (control system 334, col. 34:45-57) set the range of azimuths responsive to the determination of the tissue that is not to be targeted.

7. The apparatus according to claim 5, wherein the detection functionality comprises an ultrasound transducer ("ultrasound probes" is synonymous to ultrasound transducer – see col. 16:54).

8. The apparatus according to claim 5, wherein the detection functionality comprises at least a portion of the ultrasound array ("ultrasound probes" is synonymous to ultrasound array – see col. 16:54).

9. The apparatus according to claim 5, wherein the detection functionality comprises imaging functionality (imaging disclosed in col. 3:53-57, col. 16:30-33, col. 16:53-56, and col. 34:51).

12. A method for ablating tissue of a subject, comprising: inserting an ultrasound array having an axis into a body of the subject, adjacent to the tissue; and actuating the ultrasound array in a phased array mode to apply ablating ultrasound energy to the tissue in a range of azimuths, with respect to the axis, that is less than 360 degrees. See all Sliwa claims excluding claim 6.

16. The method according to claim 12, wherein actuating the ultrasound array comprises: determining tissue of the subject that is not to be targeted by the ablating energy (col. 16:30-33); and applying the ablating energy responsive to the determination (control system 334, col. 34:45-57) of the tissue that is not to be targeted.

18. The method according to claim 16, wherein determining the tissue that is not to be targeted comprises transmitting non-ablating ultrasound energy (imaging disclosed in col. 3:53-57, col. 16:30-33, col. 16:53-56, and col. 34:51) at the tissue that is not to be targeted.

20. The method according to claim 16, wherein determining the tissue that is not to be targeted comprises imaging the tissue that is not to be targeted (imaging disclosed in col. 3:53-57, col. 16:30-33, col. 16:53-56, and col. 34:51).

21. The method according to claim 16, wherein determining the tissue comprises

performing a measurement (temperature, col. 7:25-35) in a vicinity of the ultrasound array.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 13-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sliwa.

Sliwa discloses more than one transducer, but not "between about 32 and 42". See col. 7:15-17, *inter alia*.

Sliwa is silent regarding azimuths. However, Sliwa discusses feedback control of the transducer-to-tissue angle (fig. 67, col. 30:55-65), making obvious to one of ordinary skill in the art claims 13-15 and 17 all claiming different ranges of azimuths. (The office contends that through routine experimentation one of ordinary skill in that art would determine the claimed ranges of azimuths as well as number of ultrasound transducers. The motivation to do so is the inherent desire to optimize the device.)

Claims 8, 11, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sliwa in view of Crowley et al. (6,004,269).

Sliwa is silent regarding imaging transducers being adjacent to ablation transducers (making the image transducer part of the array) at the distal portion of the catheter and an external imaging transducer/detection functionality.

Crowley discloses an analogous ultrasound catheter in which imaging transducers (416) are adjacent to ablation transducers (414) at the distal portion of the catheter. See figure 32a. Crowley also discloses an external visualizing ultrasound device in col. 29:35-37. The motivation to combine the patents is to better define what is suggested in Sliwa (the suggestion of ultrasound imaging) as well as to provide a specific means to visualize the targeted and non-targeted tissue.

Therefore, at the time of the invention in would have been obvious to one of ordinary skill in the art to modify Sliwa in view of Crowley by using an external visualizing ultrasound device or an internal ultrasound transducer for visualizing at the distal tip of the catheter. Again, the motivation to combine the patents is to better define what is suggested in Sliwa as well as to provide a specific means to visualize the targeted and non-targeted tissue. Sliwa suggests imaging as well as using transducers for purposes other than ablation in col. 3:53-57, col. 16:30-33, col. 16:53-56, col. 34:51, and col. 7:25-27.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Smith et al. (6,066,096), Pless et al. (6,645,202), Maguire et al. (6,652,515), Cain (5,590,657).

Double Patenting

The **nonstatutory** double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed **terminal disclaimer** in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 of **copending Application No.** 10/304,500. Although the conflicting claims are not identical, they are not patentably distinct from each other because both groups of claims disclose ultrasound ablation at the pulmonary vein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
February 20, 2006

ROY D. GIBSON
PRIMARY EXAMINER